

REMARKS

Reconsideration of the present application is respectfully requested.

Status of the Claims

Claims 10-30 remain pending in the application.

Claim Rejections-35 USC §103

Claims 10-12, 16-19, 23-26 and 29-30 were rejected under 35 U.S.C. §103(a) as being unpatentable over ONO et al. U.S. 5,080,908 ("ONO") in view of FOUACHE et al. US 6,630,586 B1 ("FOUACHE"). This rejection is respectfully traversed for the reasons below.

ONO was offered for teaching preparing vitamin B₁₂-containing granules from an adsorbent carrier of starch and dextrin, with about 5-30% dextrin. ONO mentions that the dextrin may be maltodextrin. The Official Action recognized that ONO fails to disclose or suggest the claimed branched maltodextrin having between 15 and 35% of 1-6 glucoside linkages.

FOUACHE was offered for teaching branch maltodextrins as claimed.

The position of the Official Action was that it would have been obvious to one of ordinary skill in the art to use the method of granulation taught by ONO, and substitute the dextrin of ONO with the maltodextrin of FOUACHE, as FOUACHE teaches such

branched maltodextrins are indigestible and provide an acariogenic composition.

However, the proposed combination fails to recognize the surprising and unexpected properties achieved by the claimed branched maltodextrins in a granule preparation.

As explained in the present on page 13, lines 1-4 and in Example 1 on page 17-18, the claimed branched maltodextrins are far more viscous in solution than conventional soluble fibers. Yet, the claimed branched maltodextrins are good binders for granulations.

Applicants have filed a Rule 132 declaration with this response (See, e.g., the Appendix) to also demonstrate that the claimed branched maltodextrins provide a superior granulation over a maltodextrin, e.g., as mentioned by ONO.

In the declaration, two granulations are compared based on a 10% binder and 90% of an excipient. One granulation utilizes a branched maltodextrin representative of the claims of this invention (NUTRIOSE® FB06, hereinafter, BMD) as the binder, and the other uses a potato-based maltodextrin representative of a maltodextrin suggested by ONO (hereinafter, GLUCIDEX® 1) as the binder. The excipient is a crystalline xylitol (sold by the applicant company under the brand name XYLOSORB® 90).

Wet granulation was carried out by spraying colored water with a pink coloring agent to highlight an eventual heterogeneity in the water distribution, the effectiveness of

granulation and the rate and repartition of the soluble agents in the granules obtained. The variation in shading shown black and white images of figure 1 and figure 2 corresponds to the variation in the intensity of the pink coloring agent.

As shown in Figure 1, the granulation made with GLUCIDEX® 1 is not homogeneous in shading and in particles size distribution. The colored water was not uniformly absorbed by the GLUCIDEX® 1, which resulted in the heterogeneity of shading. The granulation consists of larger, darker agglomerates (A) contain large amount of coloring agent, while a large majority of non granulated powder (B) of a lighter shade corresponding to very little coloring agent and white crystals. Thus, the GLUCIDEX® 1 does not play the role of binder as the material remains crystalline.

The granulation carried out with BMD, however, as demonstrated in Figure 2, provides a granulation product with a homogeneous particle size distribution and shading, and there does not appear to be crystalline material. Consequently, despite its high viscosity, BMD is surprisingly a very good binder for granulation process.

Should the Examiner require color images of Figures 1 and 2, it is respectfully requested that the Examiner contact the undersigned.

Thus, the declaration shows the surprising and unexpected properties of the claimed branched maltodextrins, which are not recognized by the proposed combination of documents.

Therefore, the claimed invention is not obvious, and withdrawal of the rejection is respectfully requested.

Conclusion

In view of the amendment to the claims and the foregoing remarks, this application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our credit card which is being paid online simultaneously herewith for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON

/Robert A. Madsen/
Robert A. Madsen, Reg. No. 58,543
209 Madison Street, Suite 500
Alexandria, VA 22314
Telephone (703) 521-2297
Telefax (703) 685-0573
(703) 979-4709

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APPENDIX:

The Appendix includes the following item(s):

-Rule 132 Declaration of Philippe LEFEVRE.

-CV of Philippe LEFEVRE.